

REMARKS

In the Office Action dated September 16, 2005, the United States Patent and Trademark Office (hereinafter "the Office") rejected Claims 1-3 and 5 under 35 U.S.C. § 101 because these claims are said to be directed to non-statutory subject matter. The Office withdrew its reliance on U.S. Patent Application Publication No. 2002/0032582 (hereinafter "Feeney et al.") as an anticipatory reference, hence conceding that there are defects connected with Feeney et al. Claims 6, 21, and 31-34 were rejected under 35 U.S.C. § 102(e) as being anticipated by the teachings of U.S. Patent Application Publication No. 2002/0065683 (hereinafter "Pham et al."). Claims 1-5, 51, and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Feeney et al. and further in view of the teachings of Pham et al. Claims 7-10, 16-20, 22-25, 34-45, and 53-55 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Pham et al. and further in view of the teachings of Feeney et al. Applicants have amended Claims 1, 6, 16, 21, and 31 to clarify the claimed invention. Pham et al. has been overcome by an Affidavit and its exhibits under 37 C.F.R. § 1.131.

Claim 1 has also been further amended to clarify that the claimed invention is implementable by a computing device, thereby obviating the rejection under 35 U.S.C. § 101. Claims 2, 3, and 5 are dependent from amended independent Claim 1 and each of these claims recite useful, concrete, and tangible results, such as physical samples, a pad of pre-printed vouchers, or drug samples in printed form which are redeemable at a pharmacy. Under the Interim Guidelines For Examination of Patent Applications for Subject Matter Eligibility published in October 2005 by the Office, these claims contain statutory subject matter. It is indeed puzzling that the Patent Office of the United States would think that drug samples are not useful, concrete, and tangible result. If the Office continues to persist in its view, a clear and

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explicit explanation of why drug samples are not useful, concrete, or tangible result, is respectfully requested.

Prior to discussing in detail why applicants believe that all the claims in this application are allowable, a brief description of applicants' invention and brief descriptions of the teachings of the cited and applied references are provided. The following discussions of the disclosed embodiments of applicants' invention and the teachings of the cited and applied references are not provided to define the scope or interpretation of any of the claims of this application. Instead, such discussions are provided to help the Office better appreciate important claim distinctions discussed thereafter.

Background of the Invention

Traditionally, a sales representative of a pharma visits one or more prescribers, leaves behind some samples of the drugs, and waits in trust that the prescribers will prescribe these drug samples to the patients. When a sales representative visits a prescriber, the sales representative is performing two actions. First, the sales representative educates the prescriber about the efficacy of the drug samples for various disease states and differentiates them from any competitive drugs in the marketplace. Second, the sales representative leaves drug samples behind with the prescriber so that he can dispense these drug samples to his patients. For each sales representative used by the pharma, the pharma incurs numerous expenses including purchasing and maintaining an automobile for the sales representative to travel to the prescribers, as well as paying a salary, benefits, and so on. Also a growing number of billions of dollars are spent each year on everything necessary to support the distribution of drug samples, such as packaging and delivery. When this cost is multiplied by the cost of employing multiple sales representatives, the pharma cannot afford to visit all prescribers to solicit patronage of its drugs.

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But there are still other reasons beyond the economic ones that prevent the sales representative from visiting all prescribers. One or more prescribers may be located in remote areas, making it difficult for the sales representative to reach them. Certain prescribers do not wish to see a sales representative because they are too busy with their practice or they belong to an organization, such as a hospital, that forbids sales representatives from soliciting prescribers on its premises. Another reason why most prescribers are not visited by the sales representative has to do with absences by the sales representative because of parental leaves, military duties, firings, layoffs, unexpected resignations, and so on.

Summary of the Invention

Applicants' claimed invention is directed to a system for promoting and distributing pharmaceutical drugs, a drug sample fulfillment platform, a networked system for ordering pharmaceutical sample drugs, and a method for accessing a drug sample fulfillment platform. The system for promoting pharmaceutical drugs comprises a computer-readable set of ground rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber. The system further comprises a computer-implementable drug sample fulfillment platform for implementing the set of ground rules to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative.

Applicants' claimed invention also includes a system for distributing pharmaceutical drugs which comprises a drug sample fulfillment platform for accessing drug sample services, and a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples if a set of brand rules which specify drug sample availability and characteristics for the prescriber permits the prescriber to access the drug sample fulfillment platform.

Applicants' claimed invention is further directed to a drug sample fulfillment platform, which comprises a drug sample Web site for mating with a portal that is selected from a group consisting of prescriber-oriented Web portals, an e-detailing service, a Web site regarding a drug brand, and an on-line physician learning site. The drug sample fulfillment platform further comprises a request database for receiving requests of a prescriber through the drug sample Web site for drug samples. The request database responds to the prescriber by allowing the prescriber to print coupons, or to print an order form for physical samples, or pass out pre-printed vouchers if a set of brand rules allow the prescriber to receive drug samples in the form of print coupons, order forms for physical samples, or pads of pre-printed vouchers.

Applicants' claimed invention yet further includes a networked system for ordering pharmaceutical sample drugs. The networked system includes a drug sample fulfillment platform that comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink. The drug sample Web site presents the Web page including selectable options for the prescriber to order drug samples, the time frame in which those drug samples are valid for the prescriber being specified by a set of brand rules.

Applicants' invention yet further includes a method for accessing a drug sample fulfillment platform. The method comprises activating a link to access the drug sample fulfillment platform from a Web portal. The method further comprises creating a transaction that includes a prescriber identifier and a partner identifier. The method also comprises mating a drug sample Web site to the Web portal, allowing a prescriber to navigate and order drug samples only for drugs specified by a set of brand rules which include physical samples, pre-printed vouchers, and print coupons.

Pham et al. Reference

Without admitting whether Pham et al. substantially shows or describes the claimed invention, applicants submit the enclosed Affidavit and its Exhibits under 37 C.F.R. § 1.131 to overcome Pham et al. Consideration of the Affidavit and its Exhibits and withdrawal of Pham et al. as a reference is respectfully requested.

Summary of Feeney et al.

Feeney et al. explains that, in light of the substantial amount spent by pharmaceutical companies in order to maintain sample programs, "it is of utmost importance for these companies to gain access to medical offices for purposes of physician detailing and sample program monitoring." In contrast, various embodiments of applicants' invention need not access medical offices but instead prescribers access a common drug sample fulfillment platform through a Web portal. Feeney et al. describes obtaining accurate knowledge of medical office sample inventory levels to enhance the efficiency of pharmaceutical representatives by allowing them to make informed decisions regarding the appropriate timing of medical office visits and the necessary quantities of appropriate sample medications required for restocking. See paragraph 0015.

In order to gain access to medical offices, Feeney et al. designs a system that has three major components according to paragraphs 0191, 0178, and 0181: a front office server, a central server, and one or more dispensers. Note that various embodiments of applicants' invention need not invade the medical offices of prescribers by placing a front office server there to monitor the activities of prescribers. Feeney et al. specifies that the front office server and the dispensers are placed in the medical office of a physician and the central server can reside elsewhere. The reason Feeney et al. wants the front office server to be placed in a medical office is to gain access to the medical office for monitoring purposes. For example, paragraph 0191 describes that the front office server can have a database that includes the patient information, marketing content,

drug interaction information. The front office server also include a radio frequency transceiver for controlling medication dispensers. See paragraph 0192.

The central server of Feeney et al. can be configured to receive and process the determination of whether the medication is appropriate for a patient. The central server can receive tracked sample medication user information. The system of Feeney et al. includes a Web site that is connected to the central server. The Web site is configured to provide controlled user access to system information. The system information can include a financial report, an inventory report, a user's report, a regulatory report, a sales report, an order management report, a business report, and the like. A typical user includes pharmaceutical representatives, who can access specific sampling reports by accessing the appropriate Web site through any Web browser.

The dispensers of Feeney et al. are controlled by the front office server and the central server to execute medication dispensing. A large number of physician offices, each having its own front office server, communicate with a central server. Dispensing of medication can either occur automatically when a dispense command or control signal is received by the appropriate dispenser unit or manually when an authorized system user accesses the dispenser unit to physically remove the appropriate medication. The system of Feeney et al. is centered on its ability to control the dispensers. If Feeney et al. cannot control the dispensers, nothing will work in the system of Feeney et al.

The Claims Distinguished

If Pham et al. were to be withdrawn by the Office, applicants respectfully submit that all rejections must also be withdrawn, because all rejections rely on Pham et al. For clarity purposes, applicants would like to point out the defects of the remaining reference, Feeney et al. For example, none of the cited and applied references teaches "a computer-readable set of brand

rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber," as recited in Claim 1, among many other claim limitations. The Office has indicated that this limitation of Claim 1 is taught by Feeney et al. at Paragraphs 0014, 0037, and 0274-0275. This cannot be correct.

Paragraph 0014 discloses the following:

One of the problems facing pharmaceutical companies is the fact that they do not know specifically which physician within an office is sampling their medications so they cannot target appropriately. Even the most successful current sample programs only provide the pharmaceutical representative with general information regarding physician office sample usage. Pharmaceutical companies have long felt a need for data that describes sample medication usage patterns of individual physicians. Such information would allow pharmaceutical representatives to target the appropriate physicians and hope to drive increased prescription writing for those medications.

There is nothing in Paragraph 0014 that describes the recited limitation, which requires "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber." No brand rules are discussed or suggested by Feeney et al. There is nothing in Paragraph 0014 that allows a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber. Thus, no *prima facie* case of obviousness has been established by the Office.

Paragraph 0037 discloses the following:

The system for integrating data management with the process of dispensing a sample medication further can include a marketing subsystem configured to track and report the use of the sample medication. The marketing subsystem also can be configured to associate the patient information with the use of the sample medication thereby determining appropriate marketing and educational information to direct to an

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individual dispensing the sample medication and/or the patient. The system for integrating data management with the process of dispensing a sample medication can include a central server connected via a network to the sample management subsystem. The central server can receive tracked sample medication usage information from the sample management subsystem. The central server can make the sample management usage information available to an authorized user. For example, the authorized user can be a pharmaceutical company representative, or other like entity. Also, the authorized user can be a medication supplier, for example or any other like entity.

It is a mystery what Paragraph 0037 has to do with the recited limitation of Claim 1. Paragraph 0037 discloses that the physician's dispensing of sample medications is tracked, but this has nothing to do with "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber." There is nothing in Paragraph 0037 that talks about brand rules as required by the recited limitation. Thus, no *prima facie* case of obviousness has been established by the Office.

Paragraph 0274 discloses the following:

For example, the sample management subsystem collects data regarding sample usage first from the required user input, which can be entered from any computer that is attached to the local network, then from the automatic recording of specific information, such as, when the medication is removed from the sample dispenser unit. FIG. 19 is a task flow diagram of a possible sample dispensing process. The gathered data can be delivered via the local network to the front office server where it is stored and transmitted via the Internet to the central server. The central server can further process the collected data and maintain separate databases containing either raw or processed data. The processed data can be used to generate useful reports. Processed data reports provide users, such as, pharmaceutical companies and physicians with data regarding sample medication usage patterns, sample inventory levels, regulatory compliance information, and other like information.

Applicants are puzzled why Paragraph 0274 was cited for teaching the recited limitation "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause

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one prescriber's drug sample availability and characteristics to be different from those of another prescriber." Paragraph 0274 has to do with dispensing and post-dispensing procedures. No discussion pertaining to brand rules can be found and the drug sample fulfillment platform that allows the prescriber to obtain drug samples is not disclosed by Paragraph 0274. Thus, no *prima facie* case of obviousness has been established by the Office.

Paragraph 0275 discloses the following:

Because the central server also can be a website host, pharmaceutical representatives can access specific sampling reports by accessing the appropriate website through any web browser. For example, a pharmaceutical representative can access the system through a web browser linked to the central server through the Internet. The server can be configured to grant such a client access only to the categories of information that are available to the pharmaceutical representative user group. Furthermore, the specific users within a group further can be restricted to information to which they subscribe. Examples of accessible information for this particular user group are, data regarding patterns distribution of drug samples by individual physicians, real time sample drug inventory remaining in each physician office, reports regarding the effectiveness of targeted detailing, sample distribution by patient or diagnosis code, the status of specific medications by lot number or expiration date, and the like.

There is no teaching whatsoever, at Paragraph 0275, of the recited limitation "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber." Apparently, Paragraph 0275 is describing a process by which pharmaceutical representatives can obtain specific sampling reports. Thus, no *prima facie* case of obviousness has been established by the Office.

As a second example, none of the cited and applied references teaches "a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples if a set of brand rules which specify drug

sample availability and characteristics for the prescriber permits the prescriber to access the drug sample fulfillment platform," as recited in Claim 6, among other limitations.

As a third example, none of the cited and applied references teaches "a request database for receiving requests of a prescriber through the drug sample Web site for drug samples, the request database responding to the prescriber by allowing the prescriber to print coupons or to print an order form for physical samples or pads of pre-printed vouchers if a set of brand rules allow the prescriber to receive drug samples in the form of print coupons, order forms for physical samples, or pads of pre-printed vouchers," as recited in Claim 16, among other limitations.

As a fourth example, none of the cited and applied references teaches "a drug sample fulfillment platform that comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink, the drug sample Web site presenting a Web page including selectable options for the prescriber to order drug samples, the time frame in which those drug samples are valid for the prescriber being specified by a set of brand rules," as recited in Claim 21, among other limitations.

As a fifth example, none of the cited and applied references teaches "mating a drug sample Web site to the Web portal allowing a prescriber to navigate and order drug samples only for drugs specified by a set of brand rules which include physical samples, pre-printed vouchers, and print coupons," as recited in Claim 31, among many other limitations. Therefore, no *prima facie* case of obviousness has been established.

Because the Office has failed to state a *prima facie* case of anticipation or obviousness, the rejections should be withdrawn. Independent Claims 1, 6, 16, 21, and 31 are clearly patentably distinguishable over the cited and applied references. Claims 2-5, 7-10, 17-20, 22-25, 32-45, and 51-55 are allowable because they depend from allowable independent claims and

because of the additional limitations added by those claims. Consequently, reconsideration and allowance of Claims 1-10, 16-45, and 51-55 is respectfully requested.

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